40. The method of claim 34 wherein said catecholamine is selected from the group consisting of norepinephrine, epinephrine, and dopamine.

41. A method for harvesting the by-products of enhanced growth of bacteria or viruses comprising introducing an effective amount of a catecholamine to an in vitro or cell culture host medium of bacteria or virus to act directly on enhancing the growth of said bacteria or viruses, and collecting by-products other than glucose generated by said bacteria or viruses.

42. The method of claim 41 wherein said enhanced growth is effected on bacteria and said bacteria comprises Gram-negative bacteria.

REMARKS CONCERNING THE AMENDMENTS

The above amendments have been made, as requested by the Office Action, to place the claims in the Reissue Application, in the proper format for an amendment by underlying all new claims. The substance of the new claims, except for the numbering and the reference to numbering in the new claims, is identical to the original new claims 2-33 submitted with the original Reissue Application.

REMARKS CONCERNING THE REISSUE APPLICATION

A number of concerns were raised by the Examiner concerning the nature of amendments and claim structures allowed in Reissue Applications and in particular in broadening Reissue Applications. Among the general concerns and specific concerns raised as preliminary concerns in the interview were at least the following:

1. It was understood by Counsel that the position expressed by the Examiner was that claims could be amended in a broadening Reissue but that entirely new claims could not be submitted.

2. It was understood by Counsel that the position expressed by the Examiner was that the claims in the Reissue Application were for a different scope of invention than those allowed in the original patent.

3. It was understood by Counsel that the position expressed by the Examiner was that claims could not be filed in a Reissue Application that encompassed an invention more broad than the invention of the claims issued in the original Patent.

These preliminary issues raised in the interview were in addition to those issues generally raised in the Office Action. These preliminary concerns will be addressed before the response to the substantive issues raised in the Office Action are specifically responded to in another section of this Amendment.

1. It was understood by Counsel that the position expressed by the Examiner was that claims could be amended in a broadening Reissue but that entirely new claims could not be submitted. It is not understood where the basis for this concern arises. New claims are regularly raised in the filing of Reissues, whether broadening reissues or otherwise. There is no prohibition in the Rules or the MPEP on this point, and the Examiner in the interview pointed to no specific or general authority on this point.

Counsel for Applicants made a random and cursory search on Reissue Patents by number and immediately found the addition of completely new claims to be commonplace practice in the Reissue Patents already issued. For example, Counsel readily found the following Patents randomly reviewed:

Reissue 34,004 - Claims 16-19 are entirely new claims.
Reissue 34,006 - Claims 20-21 are entirely new claims.
Reissue 34,008 - Claim 21 is an entirely new claim.
Reissue 34,009 - Claims 13-21 are entirely new claims.

Reissue 34,010 - Claims 18-31 are entirely new claims.

Even this brief review of random Reissue Patents readily indicates that entirely new claims are regularly submitted and allowed to issue in Reissue Patents. This preliminary concern is not substantiated by legal authority nor confirmed by actual Patent and Trademark Office practice.

2. It was understood by Counsel that the position expressed by the Examiner was that the claims in the Reissue Application were for a different scope of invention than those allowed in the original patent.

This discussion was thought to refer to the impression that the reissue claims must be for the same "general invention" as denoted in MPEP 1412.01. However, that section of the MPEP clearly states that:

> "This does not mean that the invention claimed in the reissue must have been claimed in the original patent, although this is evidence that applicants considered it their invention. The entire disclosure, not just the claim, is considered in determining what the patentee objectively intended as his invention."

As noted in the briefing of the issues that accompanied the original application, Applicants had initially disclosed the invention broader than both the allowed claims in the Patent and the claims submitted for consideration in broadening reissue. The claims submitted in broadening reissue, however, were neither broader than canceled claims nor of equal scope to canceled claims from the prosecution history of the Patent.

3. It was understood by Counsel that the position expressed by the Examiner was that claims could not be filed in a Reissue Application that encompassed an invention more broad than the invention of the claims issued in the original Patent.

It is the very nature of a broadening reissue, as defined and authorized by the Rules of Practice to provide claims that are broader than those allowed in the original Patent. Specifically, the MPEP states that:

> "No reissued patent shall be granted enlarging the scope of the claims of the original

patent **unless applied for within two years from the grant of the original patent.**"
MPEP 1412.03

The MPEP continues with the commentary that:

"If the reissue application is timely filed within two years of the original patent grant and the applicant indicates in the oath or declaration that the claims will be broadened, then applicant may further broaden the claims in the pending reissue prosecution, even if the actual broadening occurs beyond the two year limit. [citing cases]"

It is absolutely clear that Reissue practice allows for the presenting of claims that are broader than claims allowed in the original patent. There are specific rules and case law that apply to the nature of breadth that is not allowed, but these events or situations are not present in the submitted claims, as has been outlined in detail in documents originally filed with the application and repeated, in part, herein. Those non-acceptable forms of broadening would include claims including non-elected subject matter and claims including a scope of an invention broader than or of the same scope that was canceled during the original prosecution of the Patent in order to obtain the claims of that Patent (Recapture Doctrine), and the factual basis for clearly identifying that the present claims do not fall within those exclusions has been thoroughly briefed in the earlier documents submitted at the time of filing. The Examiner is courteously requested to review the briefed issues in those documents.

It should be therefore apparent that the nature of the initial examination of this broadening reissue application, by failing to consider the claims in the proper perspective required by Section 14 of the MPEP, has not provided a satisfactory substantive examination of the legal issues in this Application, and is wrong in its appreciation of these threshold issues in the reissue application.

RESPONSE TO THE SUBSTANTIVE ISSUES RAISED IN THE FIRST OFFICE ACTION IN THIS BROADENING REISSUE APPLICATION.

Failure to Conform to the Same General Invention

The Office Action asserts that "New claims 3-22 are drawn to an invention which is not considered to conform to the same general invention as the original patent." The rejection then compares the claims, without review of either the specification or the prosecution history of the Patent. It is because of this lack of review that the erroneous conclusion has been reached.

Although the rejection has asserted that the new claims must be for the same "general invention" as denoted in MPEP 1412.01, that section of the MPEP clearly states that:

> "This does not mean that the invention claimed in the reissue must have been claimed in the original patent, although this is evidence that applicants considered it their invention. The entire disclosure, not just the claim, is considered in determining what the patentee objectively intended as his invention."

As noted in the briefing of the issues that accompanied the original application, Applicants had initially disclosed the invention broader than both the allowed claims in the Patent and the claims submitted for consideration in broadening reissue. The claims submitted in broadening reissue, however, were neither broader than canceled claims nor of equal scope to canceled claims from the prosecution history of the Patent.

The original application that ultimately issued as the Lyte patent as filed had a generic claim that recited:

"10. A method **of affecting the rate of proliferation of living organisms and vectors** following the original assessment of a need to apply a neurotransmitter chemical based on the nature of said living organisms and comprising the steps of:

(a) determining an amount of neurotransmitter chemical required to produce an effect upon said rate;

(b) **applying said neurotransmitter chemical to said living organism**;

(c) assessing efficacy of said application in step (b) in reducing or enhancing said rate; and

(d) repeating steps (a) through (c) intermittently to monitor said rate."

Similarly, original claim 18 recited:

"18. **A method of affecting the rate of proliferation of those living organisms or vectors which include at least one receptor site for interaction with neurotransmitter substances,** comprising:

(a) administering at least one neurotransmitter chemical substance in an amount adequate to affect the proliferation of said organisms;

(b) providing a nutritional environment sufficient to support said proliferation;

(c) assessing efficacy of steps (a) and (b) ; and

(d) harvesting product after a predetermined period of time."

Emphasis has been added to the original claims to point out the scope of the original claims filed. This highlighting emphasizes that the difference that the Office Action notes between the claims of the patent "suppressing the growth" of bacteria and the claims in this application "to enhance the growth of said bacteria or viruses" are within the original scope of the invention described in the original application and the continuation-in-part application subsequently filed that issued as the Lyte Patent. The two sets of claims (the allowed patent claims and the submitted Reissue Application claims) are related to the same general invention originally disclosed and originally claimed in the parent applications, "affecting the rate of proliferation."

Therefore, when the reissue claims and the patented claims are considered in this light, as required by Patent and Trademark Office procedures and rules, the inventions represented by each set of claims can be seen to be clearly related and were intended to be related in the original applications filed.

The basis for this objection should be withdrawn and the issue removed from further

consideration.

Patentably Distinct Inventions That Would Have Been Restricted

As noted in the discussion immediately above, there was a true generic claim filed in the original application and in the continuation-in-part application. In neither application was there ever a restriction requirement as between suppressing and enhancing the proliferation of an organism. The only restriction requirements that were ever applied in the applications' prosecution histories were between different mechanisms and bacteria in which the growth rate was suppressed. The assumption that an Examiner would have required a restriction requirement is erroneous on two distinct grounds:

1) There is and was a true generic claim in the application; and
2) There was no restriction requirement in the prosecution history as between suppressing and enhancing the proliferation rate of an organism.

Rather than asserting a restriction requirement, the subject matter of the generic claims as a whole was addressed in a rejection that included:

I. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Dyer et al. Or Moger et al. It was asserted that each of the references teaches the affecting of the growth of a vector or cell culture using a catecholamine. This was asserted to be what the Applicant was claiming, and therefore the claims were asserted to not be patentable.

II. Claims 1-23 were rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claim the invention. Certain terms such as "vectors," "analogs" and "derivatives" were held to be indeterminate.

III. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Kotimchenko et al. or Sumanskii et al. Each of the references was asserted to show the use of a neurotransmitter chemical to affect the growth of "living organisms." No patentable distinction was seen between the process of the

references and the process of the claims.

Therefore the Patent and Trademark Office considered the invention a true generic invention and examined the generic scope of the invention as originally claimed.

It is important to note that no restriction requirement in the Application filed on June 27, 1994 was ever asserted against the subject matter of claims presented in the Reissue Application, so there is no applicability of issues found in *In re Orita, Yahagi, and Enomoti*, 193 USPQ 145, where it was held that:

> "Although appellants undoubtedly erred by failing to file a timely divisional application in order to obtain a divisional patent, it does not follow that such error caused the original patent to be 'partially inoperative by reason of the patentee claiming less than he had a right to claim in the patent' as appellants aver in their reissue declaration under 37 CFR 1.175..."

It was further stated in *In re Orita* that:

> "...granting reissue claims substantially identical to those non-elected in application I would be ignoring the proper restriction requirement set forth in that application in which appellants acquiesced. Indeed, appellants' misapplication of section 251 would, if permitted, circumvent the copendency requirement of section 120 incorporated by reference in section."

The original restriction in the series of applications from which the present Reissue Application claims priority was against:

1) a method of diagnosing the presence of Gram-negative bacteria, including specific physical steps, none of which are recited in the claims of the Reissue Application;

2) a method of producing glucose from a lactose broth, the claim reciting specific

physical steps which are not recited in the claims of the Reissue Application;

3) a method for suppressing the growth of Gram-positive bacteria; and

4) a specific method for suppressing the growth of Gram-negative bacteria comprising the introduction of an effective blocker of catecholamine receptor sites of the organisms.

There was never a restriction requirement as between the issued subject matter of the Patent and the subject matter of the present Reissue claims. The assumption upon which this rejection is based is therefore in error as a matter of law and as a matter of the actual facts in the prosecution history of the parent application.

The only actual restriction requirement which occurred in the prosecution of the U.S. Patent Application U.S. Serial No. 08/266,805 filed on June 27, 1994 was between:

I. Claims 24 and 25, drawn to a method of suppressing the growth of Gram-positive organisms with an amount of catecholamine, classified in Class 514, subclass 727.

II. Claims 26-28, drawn to a method of suppressing the growth of Gram-negative organisms by the introduction of an effective blocker of catecholamine receptor sites of the organisms, classified in Class 514, subclass 224.8.

This basis of the rejections of record must be withdrawn.

SUMMARY OF THIS RESPONSE

Each and every issue raised during the Examiner Interview and the Office has been fully addressed and traversed in this Amendment and Response. The Examiner is earnestly requested to review the content of the "**DECLARATION FOR BROADENING REISSUE APPLICATION**" filed with the original Reissue Application. That declaration more thoroughly discusses the issues raised in this Office Action and Briefs the issues with respect to the law and Patent Rules. Applicant incorporates those comments herein, rather than merely repeating them.

Applicant suggests, that in view of the unique and complex issues of law and Patent Rules that controls this matter, the Examiner seek the legal counsel of the Solicitor's Office or Group Director with respect to the issues in this Application.

Applicant respectfully requests allowance of all pending claims in this application.

Respectfully submitted,

MARK LYTE

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Date 10 September 1999 By _____
Mark A. Litman
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents, Washington, D.C. 20231 on **September 10, 1999.**

MARC IRELAND
Name

_____
Signature